

56. (New) An aseptic container as claimed in claim 54 wherein said first sealing and retaining arrangement comprises a first rib and complementary recess formation.

57. (New) An Aseptic container as claimed in claim 56 wherein said second sealing and retaining arrangement comprises a second rib and complementary recess formation.

58. (New) An aseptic container as claimed in claim 57 wherein a rib or recess of the first rib and recess formation is subsequently used as a rib or recess that forms part of the second rib and recess formation .

59. (New) An aseptic container as claimed in claim 56 wherein the complemental recess of at least one of the first or second sealing and retaining arrangements is at least partially filled with a sealing material.

60. (New) An aseptic container as claimed in claim 54 wherein the second aseptically sealed position is deeper within the flow passage than the initial position.

REMARKS

I. Introduction

Claims 1 to 40 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested. It is also respectfully submitted that new claims 41 to 60 are allowable.

Applicants note with appreciation the acknowledgment of the claim for foreign priority and the indication that all of the certified copies of the priority documents have been received.

Applicants thank the Examiner for considering the previously filed Information Disclosure Statement, PTO-1449 paper and cited references.

II. Objection to the Specification

The Specification was objected to as not containing an abstract of the disclosure. In response, an Abstract is added herein. No new matter has been added. In addition, the Specification was objected to as having type size smaller than the minimum allowed. A new copy of the Specification having 12-point type is enclosed herewith. No new matter has been added. It is respectfully submitted that the objections to the Specification have been obviated, and withdrawal of this objection is therefore respectfully requested.

III. Objection to Claims 4 to 9, 14 to 17, 22 to 32 and 38 to 40

Claims 4 to 9, 14 to 17, 22 to 32 and 38 to 40 were objected to under 37 C.F.R. 1.75(c) as being in improper form because a multiple dependent claim recites dependency upon another multiple dependent claim. Claims 3 to 7, 12, 14 to 17, 21 to 23, 27 to 30, 35, 37, 38 and 40 have been amended herein without prejudice to remove the multiple dependencies. It is therefore respectfully submitted that all claims fully comply with the requirements of 37 C.F.R. 1.75(c), and withdrawal of these objections are therefore respectfully requested.

IV. Rejection of Claims 1 to 3, 10 to 13, 18 to 21 and 33 to 37 Under 35 U.S.C. § 102(b)

Claims 1 to 3, 10 to 13, 18 to 21 and 33 to 37 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,479,955 ("Roodvoets et al."). Applicants respectfully submit that Roodvoets et al. do not anticipate the present claims for the following reasons.

Claim 1 relates to a method of aseptically filling an internally sterilized sealed container having a transfer port which comprises a tubular body which is sealed to the wall of the container and defines a flow passage therethrough, and a sealing plug engaged into the passage, the tubular body having an annular outer sealing face thereon which surrounds the flow passage. Claim 1 recites that the method includes the steps of supporting the tubular body of the container in a selected orientation and position, and providing a sterilization and filling head having at least an outer sealing ring thereon which is adapted to engage and seal with the annular sealing face, and a sterilization chamber located inwards of and at least partially defined by the outer sealing ring. Claim 1 recites that the method includes

the steps of bringing the sterilization and filling head and the tubular body into engagement with each other so that the outer sealing ring engages and seals with the annular sealing face. In addition, claim 1 recites that the method includes the step of introducing a sterilization fluid into the sterilization chamber to sterilize at least the radially outer part of the plug and that part of the tubular body within the outer sealing ring. Claim 1 also recites that the method includes the steps of withdrawing the plug out of the tubular body in a direction away from the container whilst maintaining the sealing ring in sealed contact with the sealing face, and introducing a flowable material into the container through the tubular body. Claim 1 also recites that the method includes the steps of reinserting the plug into the tubular body to thereby close the tubular body, and disengaging the sterilization and filling head and the tubular body from each other.

Claim 10 relates to a sterilization and filling apparatus for aseptic filling of sterile containers having a filling nozzle comprising a tubular body with a flow passage there through and a plug for closing the flow passage, at least the tubular body having an annular sealing face thereon. Claim 10 recites that the apparatus includes holding means for holding the container and/or the tubular body in a selected position. Claim 10 also recites that the apparatus includes a sterilization and filling head having at least an outer annular sealing ring adapted to engage the annular sealing face on the tubular body and an inner sealing ring located inwardly of the outer sealing ring, the sterilization and filling head having a sterilization chamber located between and at least partially defined by the outer and inner sealing rings, the sterilization and filling head having a cavity therein adapted to receive the plug of a container to be filled, the sterilization and filling head and/or the tubular body being movable towards and away from the other. Claim 10 further recites that the apparatus includes sterilization fluid supply means adapted to supply sterilization fluid to the sterilization chamber. Claim 10 also recites that the apparatus includes a plug extractor adapted to extract a plug from the tubular body and move the plug into the cavity in the sterilization and filling head. In addition, claim 10 recites that the apparatus includes filling means adapted to fill the container through the sterilization and filling head when the plug has been extracted.

Claim 18 relates to an aseptic container adapted to be filled with a flowable material, the aseptic container having a filling opening comprising a tubular body having a flow passage therethrough, and a plug for sealing the flow passage.

Claim 18 recites that the plug has gripping formations on the outer face thereof, and retaining means or locking formations thereon for operatively or cooperatively locking the plug into the flow passage.

Claim 33 relates to plug and gland port for use on an aseptic container that includes a tubular body having a flow passage therethrough defined by a cylindrical inner wall of the tubular body, and a plug for sealing the flow passage, the plug having gripping formations on the outer face thereof, and retaining means or formations thereon for locking the plug into the flow passage. Claim 33 recites that the retaining means include an annular recess formed around the periphery of the plug, and an annular rib or lip formed around and standing proud of the cylindrical inner wall of the tubular body. In addition, claim 33 recites that the rib or lip is adapted to locate in the recess to form a locating and/or sealing engagement with the recess when the plug is operatively installed within the tubular body.

New claim 41 defines a method of aseptically filling an internally sterilized sealed container which is similar to that of claim 1, but including the additional limitation of the sterilization and filling head being brought into engagement with a container such that the outer sealing ring engages and seals with a sealing surface of the tubular body and an inner sealing ring engages and seals with the annular sealing face of the plug such that the inner and outer sealing rings and the portion of the transfer port extending therebetween at least partially define a sterilization chamber.

New claim 42 includes the limitation of partially re-inserting the plug into the tubular body after filling of the container, cleaning the exposed surfaces of the plug and then completing the reinsertion of the plug into the tubular body.

New claim 43 includes the limitation of re-inserting the plug into the tubular body into a second position which is deeper than the initial sealed position.

New claim 44 is directed towards a sterilization and filling apparatus having a sterilization and filling head including an outer sealing ring adapted to engage a tubular body sealing surface of the container and an inner sealing ring movable within the cavity and adapted to engage the plug sealing face of the container, with the inner and outer sealing rings at least partially defining a sterilization chamber therebetween. Claim 44 recites that a plug extractor is moveable within the inner sealing ring to engage the plug and extract the engaged

plug from the tubular body into a cavity whilst maintaining sealed contact between the inner sealing ring and the plug sealing face.

New claim 49 is directed towards a sterilization and filling apparatus including the feature of the plug extractor being adapted to re-insert the plug into a tubular body of a container after filling of the container into position which is deeper than the initial position from which the plug was extracted.

New claim 51 is directed towards a sterilization and filling apparatus having a plug extractor adapted to partially re-insert the plug sidewall into the tubular body of a container after filling of the container such that the portion of the plug sidewall remains exposed to the sterilization chamber, with the apparatus being configured such that whilst maintaining the plug in the partially re-inserted position the sterilization fluid supply can clean the exposed surfaces of the partially inserted plug.

New claim 52 is directed towards an aseptic container adapted to be filled with flowable material from a filling and sterilization head of a filling apparatus. The aseptic container has a filling opening providing an exterior sealing surface for engagement by the filling head. The opening comprises a tubular body having a flow passage therethrough. A plug for sealing the flow passage has at least one engagable formation adapted to be engaged by an engaging device of the filling head. The container further includes a first rupturable seal for aseptically sealing the plug within the flow passage prior to filling, and a sealing and retaining formation for aseptically sealing and retaining the plug within the flow passage once the container is filled.

New claim 54 is directed towards an aseptic container having a similar configuration to that of the aseptic container of claim 52. The aseptic container has a filling opening defining an exterior sterilizable surface for sterilization by the filling and sterilization head. The filling opening comprises a tubular body having a flow passage therethrough, and a plug for aseptically sealing the flow passage. An exterior portion of the plug is engagable by an engaging device of the filling head for removing and replacing the plug. A first sealing and retaining arrangement is adapted to retain the plug in the flow passage in an initial aseptically sealed position for maintaining the interior of the container in an aseptic condition prior to filling; and a second sealing and retaining arrangement is adapted to retain the plug in the flow passage in a second aseptically sealed position after the container is filled.

It is respectfully submitted that Roodvoets et al. fail to disclose, or even suggest, a sterilization and filling head having a sterilization chamber located inwards of and at least partially defined by an outer sealing ring, as recited in amended claims 1 and 10, and in new claims 41, 42, 43, 44, 49 and 51. Roodvoets et al. describe "a main sterilization chamber 41 positioned adjacent to open end 39 of housing 37, and a shaft sterilization chamber 42 positioned adjacent to the closed end 44 of housing 37." Col. 3, lines 31-33. Neither of these sterilization chambers are located inwards of and at least partially defined by an outer sealing ring as recited in amended claims 1 and 10 and new claims 41-44, 49 and 51. Moreover, as is clear from Figure 2 and column 4 lines 33-36 the sterilization chamber in operation is in fact at least constituted by the so-called main sterilization chamber 41 in conjunction with the walls of the fitting 22 and the interior of the rigid container 20.

Roodvoets et al teach a portable hand operated transfer valve (see column 3, lines 59-62) designed to be connected to filling hoses and fittings for filling of rigid typically stainless steel containers which are, unlike the container of claims 18 to 32 and claims 52 to 59 of the present invention, non-aseptic, in that they have not previously been aseptically prepared and sealed. Roodvoets et al teach removal of the plug from the valve fitting prior to sterilization as is provided by column 4 lines 33-36: "after all hoses and fittings have been properly connected, with the components in the Fig. 2 position, container 20, valve fitting 11, plug 12, and plunger 38 may be sterilized along with the interior of sterilization/fill unit 14 by admitting high pressure steam ...". It is clearly shown in Fig. 2 that the plug has been extracted from the container. Roodvoets must therefore sterilize all internal surfaces of the transfer port and the interior of the container in order to ensure that the filled container is aseptic.

In the present invention as claimed, the sterilization chamber is relatively small, being located inwardly of the outer sealing ring, and being arranged to sterilize only a relatively small exposed area of the transfer port (typically the radially outer part of the plug and that part of the tubular body within the outer sealing ring). Thus, the applied steam is able to maintain a high temperature and pressure across the entire sterilization chamber to ensure high levels of sterilization.

This is achieved as a result of the container having been previously internally sterilized and aseptically sealed. This is clearly not the case with Roodvoets et al, in which the sterilization step takes place after rather than before the plug has been extracted, owing to the non-aseptic nature of the Roodvoets container.

The aseptic container of claim 18 is thus clearly distinguishable over Roodvoets et al. The plug of Roodvoets does not disclose or suggest gripping formations on the outer face thereof. Rather, there is described "a plunger 38 that includes lugs 66 that align with notches 32 in the plug 12, thereby attaching plunger 38 to plug 12". Col 4, lines 1-21. Thus, the plug 12 does not have gripping formations on its outer face as is described in claims 18 and 33. In addition, the plug of Roodvoets is not provided with retaining means or locking formations for operatively or cooperatively locking the plug into the flow passage as is similarly set out in these claims.

With specific reference to new claim 42, Applicant respectfully submits that Roodvoets does not teach a method of filling an internally sterilized sealed container and clearly does not suggest the steps of partially re-inserting the plug into the tubular body after filling of the container, cleaning the exposed exterior surfaces of the plug and then completing the reinsertion of the plug into the tubular body. The method defined by claim 42 accordingly provides advantage over the teachings of Roodvoets in that, by cleaning the outer surface of the plug which is to later engage the inner surface of the tubular body, the engagement surface is made free of contaminants which could otherwise preclude an aseptic seal being created between the plug and the tubular body.

Applicant respectfully submits that claim 43 is patentably distinguished from Roodvoets because Roodvoets is silent as to an aseptic filling method including extracting the plug from an initial position in the tubular body and, after filling, re-inserting the plug into the tubular body in a position deeper than the initial position from which it. The transfer port can be susceptible to oxygen permeating the material of the transfer port. For some types of food product this can lead to discolouration of the product in the transfer port. By relocating the plug deeper into the tubular body, the internal volume of the tubular body is reduced and less oxygen can permeate. As a further advantage, relocating the plug in a second position different to the initial position from which the plug is withdrawn allows subsequent sealing of the plug to

the tubular body utilising an entirely fresh sealing area, such as elastomeric sealing ring 124 described with reference to Figures 23 and 24 of the present specification.

Roodvoets et al fails to suggest an aseptic filling apparatus of the type claimed in claim 44, including an inner sealing ring for engaging a plug of a container and a plug extractor for extracting the plug from the container, with the plug extractor being moveable within the inner sealing ring to engage the plug and extract the engaged plug from the tubular body into the cavity whilst maintaining sealing contact between the inner sealing ring and the plug sealing face.

Roodvoets is similarly silent on the limitation of claim 49 relating to re-insertion of the plug into the tubular body of the container after filling of the container into position which is deeper than the initial position from which the plug was extracted.

Likewise, Roodvoets et al does not teach an apparatus as newly claimed in claim 51, which is configured such that whilst maintaining the plug in the partially re-inserted position the sterilization fluid supply can clean the exposed surfaces of the partially inserted plug.

New claim 52 is clearly far removed from the teaching of Roodvoets et al. Nowhere is there taught or suggested an aseptic container having a plug with a first rupturable seal for maintaining the interior of the container in an aseptic condition prior to filling. In addition, Roodvoets et al does not disclose a sealing and retaining formation for aseptically sealing and retaining the plug within the flow passage after filling. The dust cover 72 clearly serves no sealing and retaining function in respect of the plug itself, but rather provides a totally separate and supplemental seal

Similarly, the first and second sealing and retaining arrangements of claim 54 for, respectively, retaining the plug in the flow passage in an initial aseptically sealed position prior to filling of the container, and for retaining the plug in the flow passage in a second aseptically sealed position when the container is filled are nowhere taught or suggested in this reference.

To anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in

the . . . claim.” Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements arranged as required by the claims. In re Bond, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). As more fully set forth above, it is respectfully submitted that Roodvoets et al. do not disclose, or even suggest, all of the limitations included in claims 1, 10, 18,33, 41-44, 49, 51, 52 and 54.

Additionally, to reject a claim under 35 U.S.C. § 102, the Examiner must demonstrate that each and every claim limitation is contained in a single prior art reference. See, Scripps Clinic & Research Foundation v. Genentech, Inc., 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Still further, not only must each of the claim limitations be identically disclosed, an anticipatory reference must also enable a person having ordinary skill in the art to practice the claimed invention, namely the inventions of the rejected claims, as discussed above. See, Akzo, N.V. v. U.S.I.T.C., 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986). In particular, it is respectfully submitted that, at least for the reasons discussed above, the reference relied upon would not enable a person having ordinary skill in the art to practice the inventions of the rejected claims, as discussed above. Also, to the extent that the Examiner is relying on the doctrine of inherency, the Examiner must provide a “basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flows from the teachings of the applied art.” See M.P.E.P. § 2112; emphasis in original; and see, Ex parte Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Thus, the M.P.E.P. and the case law make clear that simply because a certain result or characteristic may occur in the prior art does not establish the inherency of that result or characteristic. Accordingly, the anticipation rejection as to the rejected claims must necessarily fail for the foregoing reasons.

In summary, it is respectfully submitted that Roodvoets et al. do not anticipate claims 1, 10, 18 and 33, 41-44, 49, 51, 52 and 54.

Version with Markings to Show Changes Made

As for claims 2 to 9, which ultimately depend from claim 1, claims 11 to 17, which ultimately depend from claim 10, claims 19 to 32, which ultimately depend from claim 18, and claims 34 to 40, which ultimately depend from claim 33, claims 45-48, which ultimately depend from claim 44, claim 50 which depends from claim 49, and claim 53, which depends from claim 52, and claim 55 to 60, which ultimately depend from claim 54, it is respectfully submitted that Roodvoets et al. do not anticipate these dependent claims for at least the same reasons given above in support of the patentability of claims 1, 10, 18, 33, 41-44, 49, 51, 52 and 54.

V. Conclusion

Attached hereto is a marked-up version of the changes made to the Specification and claims by the current Amendment. The attached page is captioned "Version with Markings to Show Changes Made."

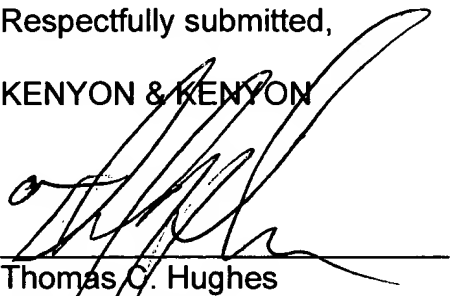
It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favourable action on the merits is earnestly solicited.

Respectfully submitted,

KENYON & KENYON

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By:


Thomas C. Hughes
Reg. No. 42,674

One Broadway
New York, New York 10004
(212) 425-7200

CUSTOMER NO. 26646

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PATENT TRADEMARK OFFICE

IN THE SPECIFICATION AND ABSTRACT:

An Abstract has been added as follows:

--Abstract

A method of aseptically filling an internally sterilized sealed container having a transfer port which comprises a tubular body which is sealed to the wall of the container and defines a flow passage therethrough, and a sealing plug engaged into the passage, the tubular body having an annular outer sealing face thereon which surrounds the flow passage, including the steps of: supporting the tubular body of the container in a selected orientation and position; providing a sterilization and filling head having at least an outer sealing ring thereon which is adapted to engage and seal with the annular sealing face, and a sterilization chamber located inwards of and at least partially defined by the outer sealing ring; bringing the sterilization and filling head and the tubular body into engagement with each other so that the outer sealing face; introducing a sterilization fluid into the sterilization chamber to sterilize at least the radially outer part of the plug and that part of the tubular body within the outer sealing ring; withdrawing the plug out of the tubular body in a direction away from the container whilst maintaining the sealing ring in sealed contact with the sealing face; introducing a flowable material into the container through the tubular body; reinserting the plug into the tubular body to thereby close the tubular body; and disengaging the sterilization and filling head and the tubular body from each other.--.

IN THE CLAIMS:

Claims 1, 3 to 7, 10 to 17, 19 to 30, 35, 37, 38 and 40 have been amended without prejudice as follows, and please add new claims 41 to 60:

1. (Amended) A method of aseptically filling an internally sterilized sealed container having a transfer port which comprises a tubular body which is sealed to the wall of the container and defines a flow passage therethrough, and a sealing plug engaged into the passage, the tubular body having an annular outer sealing face thereon which surrounds the flow passage, the method comprising the steps of:

supporting the tubular body of the container in a selected orientation and position;

providing a sterilization and filling head having at least an outer sealing ring thereon which is adapted to engage and seal with the annular sealing face, and a sterilization chamber located [within] inwardly of and at least partially defined by the outer sealing ring;

bringing the sterilization and filling head and the tubular body into engagement with each other so that the outer sealing ring engages and seals with the annular sealing face;

introducing a sterilization fluid into the sterilization chamber to sterilize at least the radially outer part of the plug and that part of the tubular body within the outer sealing ring;

withdrawing the plug out of the tubular body in a direction away from the container whilst maintaining the sealing ring in sealed contact with the sealing face;

introducing a flowable material into the container through the tubular body;

reinserting the plug into the tubular body to thereby close the tubular body;

and

disengaging the sterilization and filling head and the tubular body from each other.

3. (Amended) A method as claimed in claim 1 [or 2], wherein the method includes the steps of:

providing a gripping jaw on the sterilization and filling head within the outer sealing ring; and

gripping the plug with the gripping jaw in order to withdraw the plug from the tubular body.

4. (Amended) A method as claimed in [any one of claims] claim 2[1 to 3], wherein said method includes the steps of:

maintaining the outer sealing ring in sealing engagement with the annular sealing face on the body, and the inner sealing ring in sealing engagement with the sealing face on the plug;

gripping the plug with the gripping jaw; and

extracting the plug from the tubular body whilst maintaining the inner sealing ring in sealing engagement with the sealing face on the plug.

5. (Amended) A method as claimed in [any one of claims] claim 1 [to 4] wherein the method includes the steps of:

partially inserting the plug into the tubular body;

cleaning the peripheral outer surfaces of the plug prior to fully inserting the plug into the tubular body; and

fully inserting the plug into the tubular body.

6. (Amended) A method as claimed in [any one of claims] claim [1 to] 5, wherein the step of cleaning the peripheral outer surfaces of the plug is achieved by introducing a sterilization fluid into the sterilization chamber with the plug partially inserted into the flow passage in the tubular body.

7. (Amended) A method as claimed in [any one of claims] claim 1 [to 6], wherein the method includes the step[s] of sealing the plug to the tubular body during or after the plug has been reinserted into the tubular body.

10. (Amended) A sterilization and filling apparatus for aseptic filling of sterile containers having a filling nozzle comprising a tubular body with a flow passage therethrough and a plug for closing the flow passage, at least the tubular body having an annular sealing face thereon, the apparatus comprising:

holding means for holding the container and/or the tubular body in a selected position;

a sterilization and filling head having at least an outer annular sealing ring adapted to engage the annular sealing face on the tubular body, and an inner

sealing ring located inwardly of the outer sealing ring, the sterilization and filling head having a sterilization chamber located [within] between and at least partially defined by the outer and inner sealing rings, the sterilization and filling head having a cavity therein adapted to receive the plug of a container to be filled, the sterilization and filling head and/or the tubular body being movable towards and away from the other;

sterilization fluid supply means adapted to supply sterilization fluid to the sterilization chamber;

a plug extractor adapted to extract [a] the plug from the tubular body and to move the plug into the cavity in the sterilization and filling head; and

filling means adapted to fill the container through the sterilization and filling head when the plug has been extracted.

11. (Amended) A sterilization and filling apparatus as claimed in claim 10, wherein the [sterilization and filling head includes an] inner sealing ring which is co-axial with said outer sealing ring and spaced inwardly therefrom to define an annular space therebetween, said annular space forming said sterilization chamber, said inner sealing ring being engageable with a sealing face provided on the plug.

12. (Amended) A sterilization and filling apparatus as claimed in 10 [or 11], wherein the plug extractor may comprise one or more gripping jaws adapted to grip the plug and extract it from the tubular body into the cavity.

13. (Amended) A sterilization and filling apparatus as claimed in claim 12, wherein the jaws [may be] are mounted to ram which is moveable in an axial direction towards and away from the plug, the jaws being moveable between gripping and release positions.

14. (Amended) A sterilization and filling apparatus as claimed in claim [12 or] 13, wherein the jaws automatically move to [a] the gripping position when the ram moves in a direction away from the plug, and move into the release position when the ram moves towards the plug.

15. (Amended) A sterilization and filling apparatus as claimed in [any one of claims 12 to 14] claim 13, wherein the ram [may be] is adapted to drive the plug into the tubular passage after the container has been filled.

16. (Amended) A sterilization and filling apparatus as claimed in [any one of claims 10 to] claim 15, wherein the sterilization and filling head is adapted to shut off the flow of filling material into the container prior to the plug being fully inserted into the tubular passage.

17. (Amended) A sterilization and filling apparatus as claimed in [any one of claims 10 to 16] claim 15, wherein said sterilization and filling head is adapted to clean the plug with sterilization fluid when the plug is partially re-inserted back into the tubular passage.

20. (Amended) An aseptic container as claimed in claim 18, wherein the gripping formations will allow the application[s] of a rotational force to be applied to the plug to remove or re-install the plug into the filling opening.

21. (Amended) An aseptic container as claimed in [any one of claims 17 to 20] claim 18, wherein the plug is removed and reinstalled into said opening by axial means, and said retaining means provide an [preferably of a slide or] interference fit.

22. (Amended) An aseptic container as claimed in [any one of claims 17 to 20] claim 18, wherein said plug and opening include a screw thread or cam or bayonet locking means.

23. (Amended) An aseptic container as claimed in [any one of claims 17 to 20] claim 18, wherein the plug is cup shaped having an end wall and a cylindrical skirt depending from the end wall, the end wall adapted to be outermost when the plug is inserted into the flow passage.

24. (Amended) An aseptic container as claimed in claim 23, wherein the gripping formations are formed on the end wall and project in a direction which is opposite to that in which the skirt extends from the end wall.

25. (Amended) An aseptic container as claimed in claim 24, wherein said gripping formations [may] take the form of a head which stands proud of the end wall.

26. (Amended) An aseptic container as claimed in claim 25, wherein said head is undercut to provide purchase for [the] gripping jaws which [is] are adapted to extract the plug from the flow passage.

27. (Amended) An aseptic container as claimed in [any one of claims] claim 18 [to 26], wherein said locking formations [may] comprise a radially outwardly projecting annular rib formed on the plug, said rib being adapted to located behind a shoulder, end face or within a groove formed in or adjacent the flow passage.

28. (Amended) An aseptic container as claimed in [any one of claims] claim 18 [to 27], wherein said flow passage and/or the plug have an annular seal therein adapted to seal with a plug inserted into the [annular] flow passage.

29. (Amended) An aseptic container as claimed in [any one of claims] claim 18 [to 28], wherein the plug and/or the tubular body are formed of a thermoplastic material adapted to bond together under temperatures of between about 130°C and 180°C.

30. (Amended) An aseptic container as claimed in [any one of claims] claim 18 [to 29], wherein the plug and the tubular body are sealed together during manufacture.

35. (Amended) A plug and gland as claimed in claim [33 or] 34, wherein said sealing ring is a low melt sealant deposited in said recess.

37. (Amended) A plug and gland as claimed in [any one of claims 33 to] 36, wherein the annular recess on the plug is spaced a second distance away from operatively outer end face of the tubular body.

38. (Amended) A plug and gland as claimed in [any one of claims] claim 33 [to 37], wherein said plug has a second annular recess formed around the periphery thereof, said second annular recess being spaced from the first annular recess, the second annular recess being spaced a distance away from the operatively outer end face of the plug by a distance which is substantially the same as distance which the rib or lip is spaced away from the operatively outer end face of the gland so that when the rib or lip is located within the second annular recess the operatively outer end faces of the gland and the plug are substantially flush with each other.

40. (Amended) A plug and gland, as claimed in [any one of claims] claim 33 [to 39], wherein said rib or lip has a generally triangular form in cross section so as to provide a chamfered or bevelled face in both an outwardly facing direction and an inwardly facing direction to allow for simplified engagement and disengagement of the plug with the gland.

41. (New) A method of aseptically filling an internally sterilized sealed container from a sterilizing and filling head through a transfer port of the container, the transfer port comprising a tubular body sealed to a wall of the container and defining a flow passage therethrough, and a removable sealing plug engaged in said flow passage and having an annular sealing face, the tubular body having an exterior sealing surface, and the sterilization and filling head comprising an outer sealing ring and an inner sealing ring, the method comprising :
supporting the tubular body of the container in a selected orientation and position;

bringing the sterilization and filling head into engagement with the container
such that the outer sealing ring engages and seals with the sealing surface of the
tubular body and the inner sealing ring engages and seals with the annular sealing
face of the plug such that the inner and outer sealing rings and the portion of the
transfer port extending therebetween at least partially define a sterilization chamber;
introducing a sterilization fluid into the sterilization chamber;
withdrawing the plug out of the tubular body whilst maintaining the outer
sealing ring in sealed contact with the tubular body and whilst maintaining the inner
sealing ring in sealed contact with the plug;
introducing a flowable material into the container through the tubular body;
reinserting the plug into the tubular body to thereby close the tubular body;
and
disengaging the sterilization and filling head from the container.

42. (New) A method of aseptically filling an internally sterilized sealed
container from a sterilizing and filling head through a transfer port of the container,
the transfer port comprising a tubular body sealed to a wall of the container and
defining a flow passage therethrough, and a removable sealing plug sealing said
flow passage, the sealing plug having a side wall engaged into the passage, the
tubular body having an exterior sealing surface, the sterilization and filling head
including an outer sealing ring, the method comprising :

supporting the tubular body of the container in a selected orientation and
position;

bringing the sterilization and filling head into engagement with the container
such that the outer sealing ring engages and seals with the sealing surface of the
tubular body, the portion of the transfer port within the outer sealing ring providing a
surface of a sterilization chamber;

introducing a sterilization fluid into the sterilization chamber to sterilize the
surfaces of the sterilization chamber;

withdrawing the plug out of the tubular body whilst maintaining the outer
sealing ring in sealed contact with the tubular body;

introducing a flowable material into the container through the tubular body;
partially reinserting the plug into the tubular body such that a portion of the
plug side wall remains exposed to the sterilization chamber;
cleaning the exposed surfaces of the partially inserted plug;
completing the insertion of the plug into the tubular body to thereby close the
tubular body; and
disengaging the sterilization and filling head from the container.

43. (New) A method of aseptically filling an internally sterilized sealed
container from a sterilizing and filling head through a transfer port of the container,
the transfer port comprising a tubular body sealed to a wall of the container and
defining a flow passage therethrough, and a removable sealing plug engaged into
the passage in an initial rupturable sealed position, the tubular body having an
exterior sealing surface, the sterilization and filling head comprising an outer sealing
ring, the method comprising :

supporting the tubular body of the container in a selected orientation and
position;

bringing the sterilization and filling head into engagement with the container
such that the outer sealing ring engages and seals with the sealing surface of the
tubular body, a portion of the transfer port within the outer sealing ring providing a
surface of a sterilization chamber;

introducing a sterilization fluid into the sterilization chamber to sterilize the
surfaces of the sterilization chamber;

withdrawing the plug out of the tubular body whilst maintaining the outer
sealing ring in sealed contact with the tubular body;

introducing a flowable material into the container through the tubular body;
reinserting the plug into the tubular body into a second position deeper than
the initial position to thereby seal closed the tubular body; and
disengaging the sterilization and filling head from the container.

44. (New) A sterilization and filling apparatus for aseptic filling of sterile containers having a filling nozzle comprising a tubular body with a flow passage therethrough and a plug for sealing closed the flow passage, the tubular body having an exterior sealing surface, the plug having an annular sealing face on an exterior surface of the filling nozzle, the apparatus comprising:

a sterilization and filling head comprising a cavity, an outer sealing ring adapted to engage the tubular body sealing surface of a container, and an inner sealing ring moveable within the cavity and adapted to engage the plug sealing face of the container, the inner and outer sealing rings at least partially defining a sterilization chamber therebetween,

a sterilization fluid supply adapted to supply sterilization fluid into the sterilization chamber,

a plug extractor moveable within the inner sealing ring to engage the plug and extract the engaged plug from the tubular body into the cavity whilst maintaining sealed contact between the inner sealing ring and the plug sealing face,

filling means adapted to fill the container through the sterilization and filling head when the plug has been extracted,

the plug extractor further being movable to reinsert the plug into the flow passage.

45. (New) An apparatus according to claim 44 wherein the inner sealing ring is adapted to seal with the plug sealing face by at least partially penetrating the plug sealing face.

46. (New) An apparatus according to claim 44 wherein said plug extractor moves within, and substantially independently of, said inner sealing ring such that as a plug is extracted from a container, the plug is urged more forcefully against the inner sealing ring.

47. (New) An apparatus according to claim 44 wherein said inner sealing ring is mounted on a moveable sleeve and wherein said plug extractor is mounted

within said sleeve in a manner such that the plug extractor can move independently of the sleeve.

48. (New) An apparatus according to claim 47 wherein the sliding sleeve acts as a control valve for the filling means for controlling the flow of flowable material into a container engaged by the filling head.

49. (New) A sterilization and filling apparatus for aseptic filling of sterile containers having a filling nozzle comprising a tubular body with a flow passage therethrough and a plug for closing the flow passage, the tubular body having an exterior sealing surface, the apparatus comprising:

a sterilization and filling head comprising a cavity, an outer sealing ring adapted to engage the tubular body sealing surface of a container, the outer sealing ring at least partially defining a sterilization chamber;

a sterilization fluid supply adapted to supply sterilization fluid into the sterilization chamber;

a plug extractor adapted to engage a plug and extract the engaged plug from the tubular body into the cavity; and

filling means adapted to fill the container through the sterilization and filling head when the plug has been extracted;

wherein the plug extractor is adapted to re-insert the plug into the tubular body of a container after filling of the container into a position which is deeper than the initial position from which the plug was extracted.

50. (New) A sterilization and filling apparatus according to claim 49 further comprising sealing means for sealing a re-inserted plug into the tubular body of a container.

51. (New) A sterilization and filling apparatus for aseptic filling of sterile containers having a filling nozzle comprising a tubular body with a flow passage therethrough and a removable sealing plug sealing said flow passage, the sealing

plug having a side wall engaged into the passage, the tubular body having an exterior sealing surface, the apparatus comprising:

a sterilization and filling head comprising a cavity, an outer sealing ring adapted to engage the tubular body sealing surface of a container, the outer sealing ring at least partially defining a sterilization chamber;

a sterilization fluid supply adapted to supply sterilization fluid into the sterilization chamber;

a plug extractor adapted to engage a plug and extract the engaged plug from the tubular body into the cavity; and

filling means adapted to fill the container through the sterilization and filling head when the plug has been extracted;

wherein the plug extractor is adapted to partially re-insert the plug sidewall into the tubular body of a container after filling of the container such that a portion of the plug side wall remains exposed to the sterilization chamber; and

wherein the apparatus is configured such that whilst maintaining the plug in a partially re-inserted position the sterilization fluid supply can clean the exposed surfaces of the partially inserted plug.

52. (New) An aseptic container adapted to be filled with a flowable material from a filling and sterilization head of a filling apparatus, the aseptic container having a filling opening providing an exterior sealing surface for sterilization by the filling and sterilization head, the filling opening comprising:

a tubular body having a flow passage therethrough ;

a plug for aseptically sealing the flow passage, the plug having at least one engagable formation adapted to be engaged by an engaging device of the filling head for removing and replacing the plug;

a first rupturable seal for aseptically sealing the plug within the flow passage and for maintaining the interior of the container in an aseptic condition prior to filling, and

a sealing and retaining formation for aseptically sealing and retaining the plug within the flow passage and for maintaining the interior of the container in an aseptic condition once filled.

53 (New) An aseptic container according to claim 52 wherein:
the sealing and retaining formation is adapted to seal and retain the plug within the flow passage in a second position which is different from the initial position of the first rupturable seal from which the plug is arranged to be withdrawn.

54. (New) An aseptic container adapted to be filled with a flowable material from a filling and sterilization head of a filling apparatus, the aseptic container having a filling opening defining an exterior sterilizable surface for sterilization by the filling and sterilization head, the filling opening comprising:

a tubular body having a flow passage therethrough;

a plug for aseptically sealing the flow passage, an exterior portion of the plug being engagable by an engaging device of the filling head for removing and replacing the plug;

a first sealing and retaining arrangement adapted to retain the plug in the flow passage in an initial aseptically sealed position for maintaining the interior of the container in an aseptic condition prior to filling; and

a second sealing and retaining arrangement adapted to retain the plug in the flow passage in a second aseptically sealed position after the container is filled.

55. (New) An aseptic container as claimed in claim 54 wherein wherein said first sealing and retaining arrangement includes a rupturable seal extending between the plug and the tubular body.

56. (New) An aseptic container as claimed in claim 54 wherein said first sealing and retaining arrangement comprises a first rib and complementary recess formation.

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57. (New) An aseptic container as claimed in claim 56 wherein said second sealing and retaining arrangement comprises a second rib and complementary recess formation.

58. (New) An aseptic container as claimed in claim 57 wherein a rib or recess of the first rib and recess formation is subsequently used as a rib or recess that forms part of the second rib and recess formation.

59. (New) An aseptic container as claimed in claim 56 wherein the complementary recess of at least one of the first or second sealing and retaining arrangements is at least partially filled with a sealing material.

60. (New) An aseptic container as claimed in claim 54 wherein the second aseptically sealed position is deeper within the flow passage than the initial position.

